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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Wednesday, November 17, 1999

Re: Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents. . .Proposed Rule [Docket No. 98N-0581]

To whom it may concern:

We are writing to you to express our concerns related to the proposed rule requiring that all autologous blood collections undergo mandatory testing for transfusion-transmissable diseases.

As we understand it, the goal of the rule is to reduce errors that could occur involving untested autologous blood components. Such errors might involve a) the inadvertent transfusion of such a component to an unintended recipient; b) inadvertent release of plasma for further manufacturing; or c) the consequences of inadvertent exposure to untested but infectious autologous blood should a bag break. We believe that the proposed rule does not accomplish its goals, for the following reasons:

A) Mandatory testing will not, by itself, prevent the inadvertent transfusion of a component to an unintended recipient.

Testing autologous components does not ensure safety, unless it is the intent of the FDA to preclude use of a unit with any serologic abnormality. It is our understanding that the routine discarding of autologous units with abnormal serologic results is not being considered. In the absence of such units being discarded, the testing process itself has little meaning. For example, of 143 hospitals in the New England Region of the American Red Cross (Massachusetts, Maine, New Hampshire, and Vermont), 140 accept autologous units drawn at ARC regardless of the test status. Thus, the test results are unlikely to affect any hospital's willingness to store and issue such components.

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More direct approaches should be employed. For example, we strongly support the banning the crossover of autologous components for allogeneic recipients. Furthermore, the use of prominent and unique labelling of all autologous components at the time of collection should be mandated.

B) Mandatory testing is not necessary to protect the inadvertent release of plasma for further manufacturing.

The majority of US hospitals keep, and issue, autologous collections as whole blood, both for the benefit of the patient (most transfusions are during surgery, where the volume is useful) and the blood bank (the process of autologous collection is made simpler if component preparation is not performed).* Given the relatively small number of autologous plasma components prepared each year, a more direct approach for avoiding this error would be for the FDA to preclude the use of autologous plasma for further manufacturing.

C) Mandatory testing is not necessary to protect health care workers from the consequences of exposure to untested autologous blood.

Universal precautions are widely established and followed at health care facilities around the country. Blood banks are accustomed to treating all blood specimens as potentially infectious; at BIDMC, technologists follow the rules of universal precautions in handling over 30,000 specimens per year without any knowledge of the patient's infectious disease risk. Policies and procedures exists for accidental blood exposure that are readily applicable in the rare event of exposure to a broken autologous component. Furthermore, most patients in acute care settings are not tested for blood-transmissable infections. The risks of exposure to blood and body fluids in the operating room, or emergency room, during the treatment of the patient, far exceed the risks of a blood bag accident.

The likelihood of an error resulting in an untested autologous component being transfused into an unintended recipient is extremely small. Assuming that such an error occurs once in every 80,000 transfusions,[2] and that 1 million autologous units are collected annually in the United States, the risk of an HIV infection, even if the rate of infection in autologous donors were as high as 1 in 2000, is once per 160 million units -- or once every 160 years. [3] We do not wish to minimize the importance of eliminating a problem of even this magnitude, but believe that the approach need not be as indirect, and as expensive, as mandatory testing. Instead, we favor approaches that make the process safe, streamlined, and feasible for patients and providers in appropriate settings. We urge you to reconsider the proposed mandatory test rule.

Sincerely yours,

Margot S. Kruskall, MD
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Medical Director, American Red Cross New England Region

Mark Popovsky, MD
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Reference List

1. Kruskall MS, Yomtovian R, Dzik WH, Friedman KD, Umlas J. On improving the cost-effectiveness of autologous blood transfusion practices. Transfusion 1994; 34:259-264.

2. Linden JV. Autologous blood errors and incidents. Transfusion 34, 28S. 1994.
Ref Type: Abstract

3. Kruskall MS, Cost effectiveness of autologous blood donation. N Engl J Med 1995; 333:461-462.

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